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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/622,815	08/23/2000	Rei Asakai	Q60577	4168

7590

10/22/2002

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EXAMINER

WRIGHT, SONYA N

ART UNIT

PAPER NUMBER

1626

DATE MAILED: 10/22/2002 10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/622,815

Applicant(s)

ASAKAI ET AL.

Examiner

Sonya Wright

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-36 and 39-42 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 20-36 and 40-42 is/are rejected.
- 7) ☒ Claim(s) 39 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claims 20-36 and 39-42 are pending in this application. The previous action sent on 2 7 02 is herein vacated, however, Applicant's arguments have been considered and are applicable to the new rejections.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 20, 21, 26, 29, 30, 41, 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Davis et al., US Patent 5,057,614, and claims 20, 21, 26, 40, 41 are rejected under Barth et al., US Patent 5,380,746.

Applicant claims compounds which are inhibitors of apoptosis or necrosis and which treat diseases such as inflammatory skin disorders, hypertrophic heart and heart failure. Davis et al. teach substituted pyrroles which are useful in the treatment of inflammatory or cardiovascular disorders. Barth et al. teach bis-(1H-indol-3-yl)maleinimides which are useful in treating diseases of the heart and blood vessels, inflammatory processes, and allergies.

Davis et al. teaches the species 3-(5-amino-1-methyl-3-indolyl)-4-(1-methyl-3-indolyl)-1H-pyrrole-2,5-dione and 3-(5-hydroxy-1-methyl-3-indolyl)-4-(1-methyl-3-indolyl)-H-pyrrole-2,5-dione which are examples of compounds of the instant claims. (See column 14, lines 8 and 9, and column 14, lines 34-36.) The methods of use for instant composition claims 21, 26, 29, 30, 41, and 42 are taught by Davis et al. in the abstract and in column 11, lines 28-37.

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Barth et al. teach species examples of the instant compounds in column 2, lines 60-68, column 3, in its entirety, and column 4, lines 1-48. Barth et al. teach methods of use in column 11, lines 14-19.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

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the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 20, 21, 26, 29, 30, 41, 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis et al., US Patent 5,057,614, and claims 20, 21, 26, 40, 41 are rejected as being unpatentable over Barth et al., US Patent 5,380,746.

Determination of the scope and content of the prior art (MPEP §2141.01)

Applicant claims compounds which are inhibitors of apoptosis or necrosis, and which treat diseases such as inflammatory skin disorders, hypertrophic heart and heart failure. Davis et al. teach species examples of the instant claims which are useful in the treatment of inflammatory or cardiovascular disorders. Barth et al. teach bis-(1H-indol-3-yl)maleinimides which are useful in treating diseases of the heart and blood vessels, inflammatory processes, and allergies.

Davis et al. cross embrace the instant claims in column 2, lines 26-68, and column 3, lines 1-22. In addition, Davis et al. teach species 3-(5-amino-1-methyl-3-indolyl)-4-(1-methyl-3-indolyl)-1H-pyrrole-2,5-dione and 3-(5-hydroxy-1-methyl-3-indolyl)-4-(1-methyl-3-indolyl)-H-pyrrole-2,5-dione which are encompassed by the genus of the instant claims. The species of Davis et al. supra can be found in column 14, lines 8 and 9, and column 14, lines 34-36. The methods of use for instant composition claims

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21, 26, 29, 30, 41, and 42 are taught by Davis et al. in the abstract and in column 11, lines 28-37.

Barth et al. teach bis-(1H-indol-3-yl)maleinimides which are useful in treating diseases of the heart and blood vessels, inflammatory processes, and allergies. Barth et al. cross embrace the instant claims in column 1, lines 26-68 and column 2, lines 1 and 2. Barth et al. teach species examples of the instant compounds in column 2, lines 60-68, column 3, in its entirety, and column 4, lines 1-48. Barth et al. teach methods of use in column 11, lines 14-19.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the prior arts and the instant claims is that the prior arts teach a genus which cross embraces the genus of the instant claims.

Finding of prima facie obviousness---rational and motivation (MPEP §2142-2143)

One of ordinary skill in the art would be motivated to use the teachings of Davis et al. and Barth et al. to prepare the instant compounds in the expectation that compounds which are similar in structure would have a similar use in treating diseases such as inflammatory skin disorders, hypertrophic heart and heart failure. Further motivation to use the teachings of Davis et al. and Barth et al. is provided by the species examples in the prior art references (supra).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 36 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

For rejections under 35 U.S.C. 112, first paragraph, the following factors must be considered (In re Wands, 8 USPQ2d 1400, 1404 (CAFC, 1988)):

- 1) Nature of invention.
- 2) State of prior art.
- 3) Level of ordinary skill in the art.
- 4) Level of predictability in the art.
- 5) Amount of direction and guidance provided by the inventor.
- 6) Existence of working examples.
- 7) Breadth of claims.

8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Claim 36 is directed to "preventing functional deficiency of transplanted organs, tissues or cells". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. There are a vast number of disorders related to functional deficiency of transplanted organs, tissues or cells and Applicant does not give support for "preventing" all forms of these disorders. The art pertaining to functional deficiency of transplanted organs, tissues or cells remains highly

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unpredictable. The various forms of these disorders have different causative agents, involve different cellular mechanisms, and, consequently, differ in treatment protocol. Therefore, based on the unpredictable nature of the invention and state of the prior art and the extreme breadth of the claims, one skilled in the art could not use the claimed invention without undue experimentation.

It is suggested that Applicants delete "preventing" from claim 36 in order to obviate the rejection under 35 U.S.C. 112 first paragraph.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The preamble of claim 20 refers to an "inhibitor of apoptosis" which is indefinite. It is unclear whether Applicant intends to claim compounds or compositions. It is requested that Applicant use one of the statutory classes of inventions, e.g. compound or composition, instead of "inhibitor of apoptosis".

Claims 21-36 are drawn to a "composition" of claim 20. There is insufficient antecedent basis for this limitation in the claim because claim 20 is drawn to an "inhibitor".

Claim Objections

Claim 42 is objected to for the following reason: Claim 42 refers to "said subject" and depends from claim 40. However, claim 40 does not contain a reference to a

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"subject". It appears that claim 42 should depend from claim 41, which contains a reference to a "subject".

Claim 39 is objected to for being dependent on rejected claims.

Response to Arguments

Applicant's arguments filed 8-13-02 have been fully considered but they are not persuasive. Applicant's arguments are drawn to the method of use of the claims in question. This is not a cogent argument for compound and composition claims. The recitation of intended use in a compound and composition claims has no bearing in the patentability of said claims. Therefore, rejections under 35 U.S.C. 102 and 103 have been made supra.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sonya Wright, whose telephone number is (703) 308-4539. The examiner can normally be reached on Monday-Friday from 8:00 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (703) 308-4537. The Unofficial fax phone number for this Group is (703) 308-7922. The Official fax phone numbers for this Group are (703) 308-4556 or 305-3592.

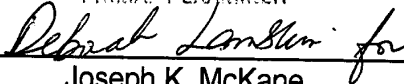
When filing a FAX in Technology Center 1600, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

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Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [joseph.mckane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-1235.

DEBORAH C. LAMBKIN
PRIMARY EXAMINER

for

Joseph K. McKane

Supervisory Patent Examiner

Group 1600

Sonya Wright

October 16, 2002